



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2011-0976; FRL-9915-62]

RIN 2070-AJ91

Toluene Diisocyanates (TDI) and Related Compounds; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Toxic Substance Control Act (TSCA), EPA is proposing a significant new use rule (SNUR) for 2,4-toluene diisocyanate, 2,6-toluene diisocyanate, toluene diisocyanate unspecified isomers (these three chemical substances are hereafter referred to as toluene diisocyanates or TDI) and related compounds as identified in this proposed rule. The proposed significant new use is any use in a consumer product, with a proposed exception for use of certain chemical substances in coatings, elastomers, adhesives, binders, and sealants that results in less than or equal to 0.1 percent by weight of TDI in a consumer product. In addition, EPA is also proposing that the general SNUR article exemption for persons who import or process these chemical substances as part of an article would not apply. Persons subject to the SNUR would be required to notify EPA at least 90 days before commencing any manufacturing or processing. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0976, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Katherine Sleasman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-7716; e-mail address: sleasman.katherine@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or distribute in commerce chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical and Allied Products Manufacturers (NAICS code 32411).
- Petroleum Refining (NAICS code 325 and 32411).
- Paints, coatings and adhesives manufacturing (NAICS code 3255).
- Urethane and other foam product manufacturing (NAICS code 326150).
- Transportation polyurethane foam products (NAICS code 32615011).
- Building and construction polyurethane foam products (NAICS code 32615031).
- Products made of foam other than polystyrene or polyurethane (NAICS code 32615091).
- All other miscellaneous polyurethane foam products (NAICS code 32615061).
- Consumer and institutional polyurethane foam products (NAICS code 32615051).
- Packing polyurethane foam products (NAICS code 32615021).
- Elastomers (NAICS code 326199).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any

persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after *[insert date 30 days after the date of publication in the **Federal Register**]* are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What Action Is the Agency Taking?

EPA is proposing a SNUR for 2,4-toluene diisocyanate, 2,6-toluene diisocyanate, toluene diisocyanate unspecified isomers (these three chemical substances are hereafter referred to as toluene diisocyanates or TDI) and related compounds. The proposed significant new use is: Any use in a consumer product of any chemical substance listed in Table 1 of Unit II.A.; and any use in a consumer product of any chemical listed in Table 2 of Unit II.A. (except for use in coatings, elastomers, adhesives, binders, and sealants that results in less than or equal to 0.1 percent by weight of TDI in a consumer product).

This proposed significant new use rule would apply to the uses EPA has identified in this unit that EPA believes are not ongoing at the time of this proposed rule. EPA is requesting public comment on this proposal, and specifically on the Agency's understanding of ongoing uses for the chemicals identified in Table 1 of Unit II.A and Table 2 of Unit II.A. in consumer products. EPA is particularly interested in whether there are any ongoing uses of these chemicals in consumer products of which the Agency is currently unaware and would welcome specific documentation of any such ongoing uses. A consumer product is defined at 40 CFR 721.3 as: a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreational settings.

This proposed SNUR would require persons that manufacture (including import) or process any of the chemicals for a significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such manufacture or process of the chemical substance for a significant new use. For this proposed rule, EPA is proposing that the general SNUR article exemption at 40 CFR 721.45(f) for persons who import or process chemical substances as part of an article would not apply. The article exemption at 40 CFR 721.45(f) is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles (see September 5, 1984; 49 FR 35014; FRL-2541-8)(Ref. 1). However, TDI and related compounds are volatile and as such could migrate out of articles that contain them. For instance, studies of TDI in polyurethane products reported that after the reaction between an isocyanate and an alcohol to form polyurethane products, residual levels of isocyanates were detected on the surface of the products, (e.g. flexible foams), which if used could lead to exposure (Refs. 2 and 3). Because TDI and related compounds are known to be volatile chemical substances, have been reported to migrate from products, are

sensitizers, and would be expected to present a higher potential for exposure if the TDI in the article were a consumer product, EPA would like the opportunity to evaluate such potential uses in consumer products for any associated risks or hazards that might exist before those uses would begin.

D. Why Is the Agency Taking this Action?

These SNURs are necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of TDI and related compounds for new uses that may produce changes in human and environmental exposures. The rationale and objectives for this SNUR are explained in Unit III.

E. What are the Estimated Incremental Impacts of this Action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this proposed rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here. In the event that a SNUN is submitted, costs are estimated to be less than \$8,589 per SNUN submission for large business submitters and \$6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. The proposed SNUR would require first-time submitters of any TSCA section 5 notice to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account before they may submit a SNUN, for a cost of \$200 per firm. However, these activities are only required of first-time submitters of section 5 notices. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or

intended export to a particular country, which is estimated to be \$84.22 per notification. The rule may also affect firms that plan to import or process articles that contain TDI and related compounds, because, while not required by the SNUR, these parties may take additional steps to determine whether TDI and related compounds are part of the articles that they are considering to import or process. Since EPA is unable to predict whether anyone might engage in future activities that would require reporting, potential total costs were not estimated.

II. Chemical Substances Subject to this Proposed Rule

A. What Chemicals Are Included in the Proposed SNUR?

This proposed SNUR would apply to TDI and its related compounds listed in Table 1 of this unit and Table 2 of this unit in consumer products. Diisocyanates contain free isocyanate functional groups ($-N=C=O$). Diisocyanates are combined with other compounds that contain free hydroxyl functional groups (i.e., $-OH$), typically called “polyols.” These two-part components react and begin to form polyurethane polymers. This chemical reaction is completed when all of the isocyanate functional groups are bound within the polymer network. This process is commonly referred to as “curing.” Products that contain free isocyanate functional groups are intended to react further and undergo “curing” in the process of use. The chemical substances subject to this proposed SNUR contain free isocyanate functional groups and are by definition uncured. Prior to complete curing, consumers and bystanders can potentially be exposed to isocyanates through both dermal and respiratory routes. Exposures to uncured isocyanates could lead to sensitization.

To ascertain if TDI and related compounds are used in consumer products, EPA reviewed published literature, the most recent data from EPA’s Chemical Data Reporting program (CDR), and communicated directly with manufacturers and processors. Reporting

under the CDR indicated no consumer uses of TDI or related compounds. However, during conversations between EPA personnel and manufacturers and processors, it was revealed that in some cases consumer products may still contain residual TDI of no more than 0.1 percent by weight, as noted in Table 2 of this unit (Ref. 4). This was also confirmed by review of published literature and SDS for consumer adhesives and sealants available in retail outlets. It is EPA's understanding that any TDI present in a coating, adhesive, elastomer, binder or sealant consumer product is at levels of no more than 0.1 percent by weight and would typically be considered residual diisocyanate remaining from the manufacture of a polyurethane polymer, a concentration which is above the detection level (Ref. 5). EPA believes that other consumer products do not contain TDI or related compounds at any level.

Table 1 – Toluene Diisocyanate Related Compounds Subject to this Action with a Proposed Significant New Use of "Any Use in a Consumer Product"

Chemical Name	Chemical Abstracts Index Name	Chemical Abstracts Service Registry Number (CASRN)
Toluene diisocyanate trimer	Benzene, 1,3-diisocyanatomethyl-, trimer	9019-85-6
Poly(toluene diisocyanate)	Benzene, 1,3-diisocyanatomethyl-, homopolymer	9017-01-0
Toluene diisocyanate dimer	1,3-Diazetidene-2,4-dione, 1,3bis(3-isocyanatomethylphenyl)-	26747-90-0
Toluene diisocyanate "cyclic" trimer	1,3,5-Triazine-2,4,6(1H,3H,5H)trione, 1,3,5-tris(3isocyanatomethylphenyl)-	26603-40-7

Table 2 – Toluene Diisocyanates Subject to this Action with a Proposed Significant Use of "Any Use in A Consumer Product (Except for use in Coatings, Adhesives, Elastomers, Binders, and Sealants at Less than or Equal to 0.1 Percent in a Consumer Product)"

Chemical Name	Chemical Abstracts Index Name	Chemical Abstracts Service Registry Number (CASRN)
2,6-Toluene diisocyanate	Benzene, 1,3-diisocyanato-2-methyl-	91-08-7
2,4-Toluene diisocyanate	Benzene, 2,4-diisocyanato-1-methyl-	584-84-9
Toluene diisocyanate unspecified isomer	Benzene, 1,3-diisocyanatomethyl-	26471-62-5

B. What Are the Production Volumes and Uses of TDI and Related Compounds?

TDI and the related compounds are generally high production volume chemicals, predominantly used in the production of polyurethanes. There are many types of polyurethane products in the marketplace, with foams representing the largest sector of the polyurethane industry. Flexible foam is primarily used for cushioning, while rigid foam is used mainly for insulation (Ref. 6). Approximately 90 percent of TDI, typically a mixture of toluene diisocyanate isomers, is used in the production of flexible foams, which are designed to be fully cured in a final product. Non-foam polyurethane use sectors of TDI include coatings, adhesives, elastomers, binders, and sealants. These products may be sold and used, most often in a mixture of formulated product, in an uncured form. Because of its hazards, some industry representatives assert that TDI is used in products intended for industrial use only (Ref. 7). In contrast, EPA believes coatings, adhesives, elastomers, binders, and sealants used by general consumers contain residual TDI of no more than 0.1 percent by weight. Due to the projected growth of the market for such use in consumer products as discussed further in Unit II.D., EPA is concerned that consumer products in the future might contain amounts of TDI above these levels. Therefore, EPA is proposing this action to provide the Agency with an opportunity to evaluate such potential uses in consumer products for any associated risks or hazards that might exist before those uses would begin.

C. What Are the Potential Health Effects of TDI and Related Compounds?

In acute, subacute, and chronic animal exposure studies for TDI, the respiratory tract was the target organ, with nasal irritation evident at concentrations above 0.1 ppm and effects becoming more severe with increasing concentration (Ref. 8). TDI is uniformly distributed throughout the body, following inhalation exposure (Refs. 8 and 9). TDI causes skin, eye, and lung irritation, progressive impairment of lung function with long-term inhalation exposure and is a respiratory sensitizer via both the dermal and inhalation routes of exposure in animals (Ref. 8).

Most data on human health hazards resulting from diisocyanate exposures are from occupational populations rather than exposures to consumer products. As discussed in the Toluene Diisocyanate and Related Compounds Action Plan (Ref. 10), diisocyanates, including TDI and related compounds, are well-known dermal, eye, and inhalation irritants and sensitizers based on worker data. They have been documented in the workplace to cause asthma and respiratory problems, such as hypersensitivity pneumonitis, an inflammation of the lungs. In severe cases, there have been reported fatal reactions.

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (Refs. 11 and 12). Once a worker is sensitized to diisocyanates, subsequent exposures can trigger severe asthma attacks. Spray application and heated processes are associated with higher incidences of asthma than other application methods because they can generate airborne isocyanate vapors and mists, which lead to worker exposure via the respiratory and dermal routes. Most workers who develop diisocyanate asthma have experienced long periods of exposure (months or longer); however, the minimum exposure to isocyanates that can elicit sensitization responses or asthma is unknown. In addition, immune response and subsequent

disease in humans can vary significantly between individuals (Ref. 6). Fatalities linked to diisocyanate exposures in sensitized persons have been reported (Refs. 13 and 14).

The International Agency for Research on Cancer (IARC) classified toluene diisocyanates as “possibly carcinogenic to humans” (Carcinogenicity Group 2B), based on inadequate evidence for the carcinogenicity of TDI in humans and sufficient evidence for the carcinogenicity of TDI in experimental animals (Ref. 15). TDI has also been classified by the European Commission (EC) as Category 3 for carcinogenicity (“causes concerns for humans owing to possible carcinogenic effects”) (Ref. 16) and by the United States National Toxicology Program (NTP) as “reasonably anticipated to be a human carcinogen” (Ref. 17). National Institutes for Occupational Safety and Health (NIOSH) considers TDI to be an occupational carcinogen and recommends exposure reduction to the lowest feasible levels (Ref 18).

There are very few reports available regarding non-occupational health effects from exposures to TDI products. However, there are case reports suggesting that paraoccupational (brought outside of the workplace) asthma may have resulted from incidental exposure to TDI, one of which involved incidental exposure to varnishing products (Ref. 19). A specific, potential concern for consumer products is exposures to children. Children exposed to the same levels of TDI vapor as adults may receive a larger dose because they have greater lung surface area to body weight ratios and increased respiratory minute volumes to weight ratios. TDI vapor is heavier than air and may layer close to the floor; therefore, children who crawl, roll, or sit on surfaces treated with chemicals (i.e. carpets and floors) and play with objects such as toys where residues may settle could potentially receive higher doses of inhaled toxicants than adults present in the same room (Ref. 20).

D. What Are the Potential Route and Sources of Exposure to TDI and Related Compounds?

There is available information on worker exposures to industrial products containing TDI, such as coatings, adhesives, and sealants. Exposures resulting from the use of these industrial products may indicate potential but lower level exposures that may result for users conducting similar activities with consumer products containing residual TDI. There is a potential for worker exposure to TDI in all industrial and commercial settings where TDI is present (Ref. 7). Because of the high volatility of TDI, exposure can occur in all phases of its use, even in the final product (Ref.17), and it is unknown to what extent factors such as application techniques, product composition, and environmental conditions influence the availability of TDI in products. One activity where overexposures have been documented is floor finishing in both personal and area samples in one NIOSH evaluation (Ref. 21). Exposure data for professional workers may provide an indication of possible exposures if consumer products and articles were to contain residual TDI.

As previously discussed, TDI is used in coatings, adhesives, sealants, and other polyurethane products. TDI is used in the manufacturing process of the polymer and as a result, a small percentage of TDI may be present in consumer products, including articles. Further, researchers looking at workplace exposures to diisocyanates have noted an increase in the number of isocyanate-containing products used by consumers (Ref. 6). In addition, consumer use of adhesives and sealants is a potential growth sector as seen in the increasing numbers of “Do It Yourself” (DIY), energy-conscious homeowners doing more of their own home renovation and repair work, as well as from craftsmen and consumers generally continuing to use adhesives (Ref. 22). Most consumers would be unaware of the potential hazards of consumer products, including articles, containing TDI or other diisocyanates. Consequently, insufficient and inadequate hazard communication may lead to incorrect use and increased consumer and bystander exposures, particularly for sensitive groups, such as children. For example, exposures

to bystanders and building occupants (including children) to TDI in industrial products have been reported in the literature, including emissions of TDI from concrete patio sealants (Refs. 23 and 24) and detection of TDI in building air samples following use of urethanes containing TDI to coat wood floors (Ref. 25). It is possible that lower level exposures could occur when conducting comparable activities using similar types of consumer products containing residual TDI. Even if consumers are aware of such potential hazards, they may not take appropriate precautions or research the appropriate resources in which these precautions are addressed. Of particular concern is the fact that children may have a greater potential for exposure if they use or are bystanders to the use of consumer products containing even residual amounts of TDI, because they may not have fully developed judgment for following labeling instructions and safety precautions and may not cease activity even when they are experiencing symptoms of exposure.

III. Rationale and Objectives

A. Rationale

Diisocyanates are potent dermal and lung sensitizers and an attributable cause of work-related asthma worldwide (Ref. 26). In the past, consumer exposures have not been a focus of concern with respect to diisocyanates, because it had been assumed that consumers were generally exposed to products containing only completely cured polyurethanes, which have been generally considered to have low toxicity (Ref. 2). However, an increase in consumer use of polyurethane products that may further react and undergo “curing” could occur if consumer products, such as coatings, elastomers, adhesives, and sealants contained TDI in amounts greater than residual amounts. In such instances, TDI and related compounds that are not completely reacted upon their application can provide potential exposures both to the consumer as the direct user or to

bystanders when products are used by others (Refs. 2 and 3). In sensitized individuals, exposure to even small amounts of diisocyanates may cause allergic respiratory reactions like asthma and severe breathing difficulties (Ref. 6). EPA believes that the use of any of these chemical substances in consumer products above current levels could significantly increase human exposure, and that such increase should not occur without an opportunity for EPA review and control as appropriate. As discussed in Unit II., regarding the chemicals listed in Table 2 of Unit II.A., based on Safety Data Sheets (SDS) information that coating-, adhesive-, elastomer-, binder-, or sealant-consumer products may contain residual TDI of no more than 0.1 percent by weight, EPA believes that these consumer products do not contain residual TDI of more than 0.1 percent by weight. EPA believes that other consumer products do not contain TDI or related compounds at any level.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

B. Objectives

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new use(s) that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture or process TDI or its related compounds (see Table 1 of Unit II.A. and Table 2 of Unit II.A.) for the described significant new use before that activity begins.

2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing TDI or its related compounds (see Table 1 of Unit II.A. and Table 2 of Unit II.A.) for the described significant new use.

3. EPA would be able to regulate prospective manufacturers or processors of TDI or its related compounds (see Table 1 of Unit II.A. and Table 2 of Unit II.A.) before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

1. The projected volume of manufacturing and processing of a chemical substance.
2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of TDI or its related compounds subject to this proposed rule, as discussed in this unit, EPA considered relevant information about the toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA has preliminarily determined as the significant new uses: any use in a consumer product for any chemical listed in Table 1 of Unit II.A.; and any use in a consumer product for any chemical listed in Table 2 of Unit II.A. (except for use in coatings, elastomers, adhesives, binders, and sealants that results in less than or equal to 0.1 percent by weight of TDI in a consumer product).

The article exemption at 40 CFR 721.45(f) is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles (see September 5, 1984; 49 FR 35014,)(Ref. 1). However, TDI and related compounds are volatile and as such could migrate out of articles that contain them. For instance, studies of TDI in polyurethane products reported that after the reaction between an isocyanate and an alcohol to form polyurethane products, residual levels of isocyanates were detected on the surface of the products, which if used could lead to exposure (Refs. 2 and 3). Because TDI and related compounds are known to be volatile chemical substances, have been reported to migrate from products, are sensitizers, and would be expected to present a higher potential for exposure if the TDI in the article were a consumer product, EPA would like the opportunity to evaluate such potential uses in consumer products for any associated risks or hazards that might exist before those uses would begin.

EPA believes any new use of TDI and related compounds as part of articles would increase the duration and magnitude of human exposure to the substance. Based on these considerations, EPA has preliminarily determined that importing or processing substances in Table 1 of Unit II.A. and Table 2 of Unit II.A. as part of articles warrants making inapplicable the article exemption at 40 CFR 721.45(f) for the significant new uses identified in the tables in Unit II.A..

V. Importers and Processors of These Chemical Substances as Part of Articles

Once the determination of a significant new use under TSCA section 5(a)(2) has been made, EPA may separately determine whether it would be appropriate to make the regulatory exemption for some or all persons who import or process a chemical substance as part of an article (40 CFR 721.45(f)) inapplicable to a SNUR. In this case, EPA believes that the assumption underpinning this exemption, that people and the environment will generally not be exposed to chemical substances as part of articles, does not hold true. See Unit IV. for a discussion of why EPA believes this assumption is incorrect. Thus EPA is proposing to make this exemption inapplicable to importers or processors of the TDI and related compounds as part of an article for the identified significant new uses. EPA is requesting comment on the potential for exposure to these chemical substances via these articles and for comments on the ongoing uses of the TDI and related compounds as part of an article.

VI. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. However, for this action, EPA is proposing that 40 CFR 721.45(f) (which generally exempts

persons importing or processing a substance as part of an article) will not apply and a person who imports or processes a chemical substance as part of an article would not be exempt from submitting a SNUN.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6 or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. In accordance with 40 CFR 707.60(b) this proposed SNUR does not trigger export notification for articles. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. The TSCA section 13 import certification requirement applies to articles containing a chemical substance or mixture if so required by the Administrator by a specific rule under TSCA. At this time EPA is not proposing to require import certification for these chemical substances as part of articles.

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376; FRL-3658-5)(Ref. 27), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin commercial manufacture or processing of the chemical substance(s) that would be regulated through this proposed rule, if finalized, would have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule. To the extent that additional ongoing uses are found in the course of rulemaking, EPA would exclude those specific chemical substances for those specific uses from the final SNUR. EPA has promulgated provisions to allow persons to comply with the final SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUN is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required to submit only test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- Human exposure and environmental releases that may result from the significant new uses of the chemical substance,
- Potential benefits of the chemical substance, and
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

X. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this proposed rule, including as part of articles (Ref. 28). In the event that a SNUN is submitted, costs are estimated at approximately \$8,589 per SNUN submission for large business submitters and \$6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 28).

B. Export Notification

Under section 12(b) of TSCA and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical covered in this proposed SNUR, as stated in the accompanying EA of this proposed SNUR, the estimated cost of the export notification requirement on a per unit basis is \$84.22.

C. Import or Processing Chemical Substances as Part of an Article

In proposing to make inapplicable the exemption relating to persons that import or process certain chemical substances as part of an article, this action may affect firms that plan to import or process types of articles that may contain the subject chemical substance. Some firms have an understanding of the contents of the articles they import or process. However, EPA acknowledges that importers and processors of articles may have varying levels of knowledge about the chemical content of the articles that they import or process. These parties may need to become familiar with the requirements of the rule. And, while not required by the SNUR, these parties may take additional steps to determine whether the subject chemical substances are part of the articles that they are considering to import or process. This determination may involve activities such as gathering information from suppliers along the supply chain, and/or testing samples of the article itself. Costs vary across the activities chosen and the extent of familiarity a firm has regarding the articles it imports or processes. Cost ranges are presented in the “Understanding the Costs Associated with Eliminating Exemptions for

Articles in SNURs” (Ref. 29). Based on available information, EPA believes that article importers that choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis. For those companies choosing to undertake actions to assess the composition of the articles they import or process, EPA expects that importers would take actions that are commensurate with the company’s perceived likelihood that a chemical substance might be a part of an article, and the resources it has available. Example activities and their costs are provided in the accompanying Economic Analysis of this rule (Ref. 28).

XI. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory action:

A. Promulgate a TSCA Section 8(a) Reporting Rule

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for TDI, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements (see TSCA sections 8(a)(1)(A) and 8(a)(1)(B)). In view of the level of health concerns about TDI if used for the proposed significant new use, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA’s regulatory objectives.

B. Allow the Exemption for Persons Who Import or Process TDI and Related Compounds as Part of Articles That Would Be Subject to the Proposed SNUR

Under the SNUR exemption provision at 40 CFR 721.45(f), a person who imports or processes a chemical substance covered by a SNUR identified in 40 CFR part 721, subpart E, as part of an article is not generally subject to the notification requirements of 40 CFR 721.25 for that chemical substance. However, EPA is concerned that exempting TDI and related compounds as part of articles would render the SNUR less effective because of the possibility that articles could be imported or processed for uses subject to this proposed SNUR without the submission of a SNUN. This proposed rule would not include the exemption at 40 CFR 721.45(f).

XII. Request for Comment

A. Do you have comments or information about ongoing uses?

EPA welcomes comment on all aspects of this proposed rule. EPA based its understanding of the use profile of these chemicals on the published literature, the 2012 CDR submissions, market research, discussions with manufacturers, and product SDSs. To confirm EPA's understanding, the Agency is requesting public comment on the EPA's understanding that coating, adhesive, elastomer, binder, or sealant consumer products do not contain residual TDI of more than 0.1 percent by weight, as noted in Table 2 of Unit II.A.. EPA believes that other consumer products do not contain TDI or related compounds at any level. In providing comments on the concentration of TDI and related compounds in the consumer product, it would be helpful if you provide sufficient information for EPA to substantiate any assertions of use and concentrations.

B. What Should I Consider as I Prepare my Comments for EPA?

1. *Submitting CBI.* It is EPA's policy to include all comments received in the public docket without change or further notice to the commenter and to make the comments available

on-line at www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM that you mail to EPA as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. Tips for preparing your comments. When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Significant New Uses of Chemical Substances; Certain Chemicals. 49 FR 35014, September 5, 1984 (FRL-2541-8).
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Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications: NIOSH Alert. <http://www.cdc.gov/niosh/docs/2006-149/default.html>.

27. U.S. EPA. Significant New Uses of Certain Chemical Substances.

55 FR 173776, April 24, 1990 (FRL-3658-5).

28. EPA. Economic Analysis of the Significant New Use Rule for Toluene

Diisocyanate (TDI) and Related Compounds. April 2, 2014.

29. EPA, Understanding the Costs Associated with Eliminating

Exemptions for Articles in SNURs. May 1, 2013.

30. U.S. EPA. Modifications of Significant New Use Rules for Certain Substances. 62 FR

42690, August 8, 1997 (FRL-5735-4).

XIV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed SNUR has been designated by the Office of Management and Budget (OMB) as a “significant regulatory action” under section 3(f) of Executive Order (58 FR 51735,

October 4, 1993). Accordingly, EPA submitted this action to OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for an export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system. Additional burden, estimated to be less than 10 hours, could be incurred where additional record keeping requirements are specified under 40 CFR 721.125(a), (b), and (c).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR, part 9, and included on the related collection instrument, or form, if applicable. EPA is amending the table in 40 CFR part 9 to list this SNUR. This listing of the OMB control numbers and their subsequent codification in the

CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since the existing OMB approval was previously subject to public notice and comment before OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend the table is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this proposed SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

EPA generally finds that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities (See, e.g., Ref. 30). Since these proposed SNURs would require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact would occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to engage in such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2011, only three submitters self-identified as small in their SNUN submission (Ref. 28). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of

developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a “significant new use.” EPA has preliminarily determined, based in part, on the Agency’s market research, that these chemical substances are not being manufactured (including imported) or processed for a significant new use. This preliminary determination also includes importation and processing of these chemical substances as part of articles for the significant new use (Unit IV.). Therefore, based on current knowledge, EPA has preliminarily determined that these uses, including the importation of these chemical substances as part of articles, are not ongoing, and that no small entities presently manufacture for the significant new uses addressed in this proposed rule. EPA will consider information received during the comment period that might indicate that this preliminary determination is incorrect.

EPA believes that there will be minimal impact to processors and importers of these chemical substances as part of articles from this proposed SNUR. The SNUR does not require processors and importers of articles to conduct specific activities to ascertain if they are importing or processing an article that uses a chemical subject to the proposed rule. EPA expects importers would take actions that are commensurate with their perceived likelihood of a chemical substance subject to the SNUR being part of an article, and the resources it has available. EPA has no reason to believe that a firm would voluntarily incur substantial costs to comply with the SNUR, but rather EPA believes each firm will choose the most efficient route to identify whether it is importing the subject chemical substances in articles.

Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR is not expected to be significant or adversely impact a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538, do not apply to this action.

E. Executive Order 13132: Federalism

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have Tribal implications because it is not expected to have any effect (i.e., there will be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 (65 FR 67249, November 9, 2000), does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks for children.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, section 12(d) of NTTAA, 15 U.S.C.272 note, does not apply to this section.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This proposed rule does not invoke special consideration of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 7, 2015.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add §721.10789 to subpart E to read as follows:

§721.10789 Toluene diisocyanates and related compounds.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances listed in Table 1 and Table 2 of this paragraph are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table 1.—Toluene Diisocyanates ad Related Compounds Subject to Reporting for Any Use in a Consumer Product

Chemical Name	Chemical Abstracts Index Name	Chemical Abstracts Service Registry (CASRN)
Toluene diisocyanate trimer	Benzene, 1,3-diisocyanatomethyl-, trimer	9019-85-6
Poly(toluene diisocyanate)	Benzene, 1,3-diisocyanatomethyl-, homopolymer	9017-01-0
Toluene diisocyanate dimer	1,3-Diazetidine-2,4-dione, 1,3bis(3-isocyanatomethylphenyl)-	26747-90-0
Toluene diisocyanate “cyclic” trimer	1,3,5-Triazine-2,4,6(1H,3H,5H)trione, 1,3,5-tris(3isocyanatomethylphenyl)-	26603-40-7

Table 2.—Toluene Diisocyanates and Related Compounds Subject to Reporting for Any Use in A Consumer Product (Except for use in Coatings, Adhesives, Elastomers, Binders, and Sealants at Less than or Equal to 0.1 Percent in a Consumer Product)

Chemical Name	Chemical Abstracts Index Name	Chemical Abstracts Service Registry Number (CASRN)
2,6-Toluene diisocyanate	Benzene, 1,3-diisocyanato-2-methyl-	91-08-7
2,4-Toluene diisocyanate	Benzene, 2,4-diisocyanato-1-methyl-	584-84-9
Toluene diisocyanate unspecified isomers	Benzene, 1,3-diisocyanatomethyl-	26471-62-5

(2) The significant new uses are:

(i) For the chemical substances listed in Table 1 of paragraph (a)(1), any use of the chemical substance in consumer products.

(ii) For the chemical substances listed in Table 2 of paragraph (a)(1), any use of the chemical substance in a consumer product (except for use in coatings, adhesives, elastomers, binders, and sealants, that results in less than or equal to 0.1 percent by weight of such chemical substance in the consumer product).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b):

(1) *Revocation of certain notification exemptions.* The provisions of § 721.45(f) do not apply to this section. A person who imports or processes a chemical substance identified in paragraph (a)(1) of this section as part of an article for a significant new use described in paragraph (a)(2) of this section is not thereby exempt from submitting a significant new use notice.

(2) [Reserved]

[FR Doc. 2015-00474 Filed 01/14/2015 at 8:45 am; Publication Date: 01/15/2015]